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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,081	04/06/2001	Satoru OI	2559US0P	2326

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EXAMINER
ROBINSON, BINTA M

ART UNIT	PAPER NUMBER
1625	18

DATE MAILED: 04/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Applicati n No. 09/807,081	Applicant(s) OL ET AL.	
	Examiner Binta M. Robinson	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,9-15,17,18,21 and 22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9-11,14,15,17,18,21 and 22* is/are rejected.

7)☒ Claim(s) *12 and 13* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *8* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Detailed Action

The 112, second paragraph rejections of claims 16, 18-22 and the 101 rejection of claim 23 are withdrawn in light of applicant's amendment at paper no. 9/A.

The applicant's assert that the election of species does not fit within the group I genus which was created 6. While the applicant is correct, the examiner notes that the election of species also does not fit into any of the claims because R1 of formula I, claim 1 can only be equal to acyl, whereas in the elected species, R1 is substituted with biphenyl. So, the elected species does not fit into group II either. Group I was created for searching purposes, whereas Group II was held to be the non-elected group. So Group II cannot be elected since it is held non-elected, does not read on the elected species and encompasses various independent and distinct inventions that would present an undue burden on the examiner to search.

The group I genus that will be crafted around the elected species has been revised below:

Group I, claim (s) 1-7, 8-15, 17-18, and 21-22 are drawn to the compound of formula I in claim 1 where A is carbocyclic aryl substituted with halogen, B is carbocyclic group substituted with amino alkyl moiety, D is C1-C4 alkylene, E is –C(O)N(Ra), Ra is H, G is methylene or ethylene, Z is halogenated carbocyclic group, A is a halogenated phenyl ring, X is O, or unoxidized S atom, L is methylene or ethylene, R1 is an acyl group substituted with biphenyl. This Restriction Requirement is made FINAL.

(old rejections)

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7, 9-11, 14-15, 17-18, 21-22 in part are rejected under 35 U.S.C. 112, first paragraph, because the specification, does not reasonably provide enablement for R2 bonded to the atom on Ring B to form all rings. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The claims as recited are broader than the scope of enablement. The specification lacks direction or guidance for placing all of the alleged products in the possession of the public without inviting more than routine experimentation. The applicant is referred to ***In re Wands***, 858 f.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) which includes the incorporation of the 8 factors recited in ***Ex parte*** Foreman 230 USPQ 546 (Bd. Of App. And Inter 1986).

Claim 21 in part is rejected under 35 U.S.C. 112, first paragraph, because the specification, does not reasonably provide enablement for the method of treating all diseases of the various diseases claimed. It is also not established in the art to prevent diabetes or obesity with pharmaceutical drugs. Most drugs do not prevent but treat disease. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate

in scope with these claims. The claims as recited are broader than the scope of enablement.

The applicant is referred to ***In re Wands***, 858 f.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) which includes the incorporation of the 8 factors recited in ***Ex parte*** Foreman 230 USPQ 546 (Bd. Of App. And Inter 1986).

Claim(s) 22 in part are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. Regulating somatostatin receptor is a mechanism. The disease being treated by this regulation is not stated. The specification must contain one practical utility in currently available form. The regulation of an enzyme must be related to a disease that needs to be improved and this disease needs to be recited. There is no reasonable assurance that these compounds will have all of the alleged properties or have the applicants supplied the supporting data. The applicant is referred to ***In re Fouche*** 169 USPQ 429 ccpa, 1971, MPEP 716.02 B. The applicant is referred to ***In re Wands***, 858 f.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) which includes the incorporation of the 8 factors recited in ***Ex parte Foreman*** 230 USPQ 546 (Bd. Of App. And Inter 1986).

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1)the breadth of the claims, 2) the nature of the

invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art 6) the amount of direction provided by the inventor 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F. 2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).
In terms of factor 3 and 5, the state of the art and the level of predictability in the art cannot be predicted with any certainty beyond what specific test compounds /compositions and/or additional therapeutic agents should be used and are likely to provide productive results beyond those therapeutic compounds/compositions and/or additional therapeutic agents taught in the specification.

In terms of factors 4 and 6, the inventor provides no guidance beyond the therapeutic compound/compositions and/or therapeutic agents as taught in the specification as previously mentioned. As a result one of ordinary skill in the art could not predict what other types of therapeutic compounds/compositions and/or additional therapeutic agents, other than those taught in the specification; and with regards to the 7th and 8th wands factor, while the existence of working examples are limited to the aforementioned compounds/compositions as taught in the specification, an indeterminate quantity of experimentation would be necessary to determine all potential therapeutic compounds/compositions' effects on the diseases claimed.

In terms of the 8th Wands factors, undue experimentation would be required to make or use the invention based on the content of the disclosure due to the breadth of the claims, the level of predictability in the art of the invention,

and the poor amount of direction provided by the inventor. Taking the above factors into consideration, it is not seen where the instant claim is enabled by the instant application.

The elected species is allowable. Claims 12 and 13 are objected to because they are based on a rejected claim.

The IDS filed at paper no. 8 has been considered.

Response to Applicant's Remarks

112, first paragraph rejections of claims 1-1-7, 9-15, 17-18, 21-22

The applicant alleges that R2 bonding to an atom on Ring B to form a ring a ring is enabled at page 21, lines 10-22 of the specification. However, contrary to the applicant's assertion, there are no examples of R2 bonding to an atom on Ring B to form a ring at page 21, lines 10- to page 22. The applicant points to only one example, example 5 on page 125 of the specification of where R2 bonds to an atom on Ring B to form a ring. However, this is only one example, that does not represent the full breadth that R2 can represent.

Rejection of Claim 21 under 112, first paragraph, for lack of enablement of the various diseases claimed

The applicants allege that amending claim 21 to be an independent method of treating claim overcomes the 112, first paragraph rejection. However, claim 21 is still referring to the method of treating various diseases, many of which are unrelated, and are not enabled in the specification in terms of treatment with the claimed compounds in terms of experimental data.

112, first paragraph rejection of claim 22 for lack of utility

Applicant traverses the rejection of claim 22 by alleging that regulating somatostatin receptor function is understood by those skilled in the art to be an established utility. However, regulating somtostatin is a mechanism that has not been correlated in the claims to the treatment of a specific disease. This claim therefore lacks utility.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Binta M. Robinson whose telephone number is (703) 306-5437. The examiner can normally be reached on M-F (9:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on (703)308-4698. The fax phone numbers

for the organization where this application or proceeding is assigned are (703)308-7922 for regular communications and (703)308-7922 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0193.

Binta Robinson

April 4, 2003

Alan L Rotman

ALAN L. ROTMAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600